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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,685	11/28/2000	Steven G. Reed	014058-008561US	7839
20350	7590	12/17/2003		EXAMINER
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/724,685	REED ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28September2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 37-55 is/are pending in the application.
  - 4a) Of the above claim(s) 42-54 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 37-41 and 55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 37-55 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

### **DETAILED ACTION**

1. Applicants' Response to Restriction, received 29September2003, paper#16, is acknowledged.

Applicants elect, with traverse, Invention I, claims 37-41 and 55, drawn to polypeptide compositions, classified in class 424, subclass 248.1. The traversal is on the grounds that all three inventions stem from a common concept and theory and therefor related. In addition, prosecution of all claims would not place a substantially greater burden on the examiner. This is not found persuasive because of the reasons put forth in the original Restriction Requirement, i.e., the three distinct inventions have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive. Therefor, the requirement is still deemed proper and is therefore made FINAL.

Claims 42-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim 37 has been amended.

2. Claims 37-41 and 55 are under consideration.

### **Drawings**

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### **Priority Statement**

4. The status of all U.S. Patent applications in the priority statement at the beginning of the specification should be updated. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising amino acid sequence SEQ ID NO:107 wherein said polypeptide is immunogenic, binds to antibodies, and stimulates T-cells, does not reasonably provide enablement for vaccine compositions comprising said polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - A vaccine comprising an isolated polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:107 or a fusion protein comprising said polypeptide; and a physiologically acceptable carrier.

The state of the prior art - In the prior art field of *Mycobacterium tuberculosis* vaccines, vaccines which comprise isolated polypeptides of *Mycobacterium tuberculosis* have

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been demonstrated in animal models. However, the effectiveness relies upon which polypeptide is being utilized.

The predictability or lack thereof in the art - therefor, there is not an *a priori* predictability of success for individual *M. tuberculosis* polypeptides against infection with *M. tuberculosis*.

The amount of direction or guidance present - the instant specification teaches isolation of the claimed polypeptide and said polypeptide's ability to induce an antibody response or to react with primed T-cells.

The presence or absence of working examples – the instant specification provides insufficient guidance and no working examples, in animal models or humans, of the claimed invention, i.e., a vaccine.

The quantity of experimentation necessary to determine whether the claimed polypeptide is effective as a vaccine and the parameters of presentation, dosage, etc., constitutes merely an invitation to experiment without a reasonable expectation of success.

7. Claims 37-41 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 37 recites "An isolated polypeptide comprising *an* amino acid sequence as set forth in SEQ ID NO:107." The use of the modifier "an" renders the claim indefinite because it is unknown whether the claimed polypeptide comprises the entire sequence designated as SEQ ID NO:107, or a subsequence of SEQ ID NO:107. It is recommended that the claim be amended to read "comprising *the* amino acid sequence as set forth in SEQ ID NO:107".

Claims 38-41 and 55 depend from claim 37, but do not correct the indefiniteness.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-66 of copending Application No. 10/193,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same amino sequence. In the instant claims the sequence is designated as SEQ ID NO:107 and in the claims of copending 10/193,002, the sequence is designated as SEQ ID NO:102.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,627,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a polypeptide comprising an amino acid sequence a set forth in SEQ ID NO:107 and the claims of Pat. No. 6,627,198 are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:26. SEQ ID NO:26 encompasses all of SEQ ID NO:107.

### Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

December 15, 2003